

B2 slowly mixing water with micronized progesterone, the total amount of water mixed with said micronized progesterone not exceeding the maximum wetting capacity of the amount of micronized progesterone, whereby to obtain wetted micronized progesterone;

drying said wetted micronized progesterone to form dry micronized progesterone;

mixing said dry micronized progesterone with a pharmaceutically acceptable excipient or diluent therefor; and

forming a tablet by direct compaction of said dry micronized progesterone which has been mixed with said pharmaceutically acceptable excipient or diluent therefor.

Kindly amend claim 2 to read as follows:

2. (Amended) A method for preparing a tablet for the vaginal administration of progesterone for systemic use, comprising:

slowly mixing water with micronized progesterone, the total amount of water mixed with said micronized progesterone not exceeding the maximum wetting capacity of the amount of micronized progesterone, whereby to obtain wetted micronized progesterone;

drying said wetted micronized progesterone to form dry micronized progesterone;

mixing said dry micronized progesterone with (a) a pharmaceutically acceptable non-effervescent excipient diluent therefor and (b) an effervescent; and

forming a tablet by direct compaction of said dry micronized progesterone which has been mixed with said pharmaceutically acceptable non-effervescent excipient or diluent therefor and said effervescent.

Kindly amend claim 3 to read as follows:

3. (Amended) A method according to claim 2 for preparing a tablet for the vaginal administration of progesterone for systemic use, wherein the step of mixing said dry micronized progesterone with (a) a pharmaceutically acceptable non-effervescent excipient or diluent therefor and (b) an effervescent comprises:

sieving a first lubricant to obtain a sieved first lubricant;

mixing said dry micronized progesterone with said sieved first lubricant and a material selected from a first filler or a disintegrant to form a first mixture;

mixing a binder which binds dry particles with said first mixture to form a second mixture;

intimately mixing said effervescent and a first quantity of a second filler to form a third mixture;

sieving said third mixture to obtain a sieved third mixture, and then intimately mixing said sieved third mixture and said second mixture to form a fourth mixture;

intimately mixing said fourth mixture with a second quantity of said second filler to form a fifth mixture;

sieving a second lubricant and a material selected from a saponificant or a third lubricant to obtain, respectively, sieved second lubricant and sieved third lubricant; and

intimately mixing said sieved second lubricant and said sieved third lubricant with said fifth mixture to form a sixth mixture.

Kindly amend claim 8 to read as follows:

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8. (Amended) A method according to claim 3 wherein said sieved second lubricant and said sieved third lubricant are sieved through sieves having a pore size of between about 100 and 150 microns.

Kindly amend claim 13 to read as follows:

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13. (Amended) A method according to claim 12 wherein said starch is cornstarch.

Kindly amend claim 14 to read as follows:

14. (Amended) A method according to claim 3, wherein said binder which binds dry particles is polyvinylpyrrolidone (Povidone).

Kindly amend claim 15 to read as follows:

133 15. (Amended) A method according to claim 14, wherein said binder which binds dry particles is Povidone K-30.

Kindly amend claim 36 to read as follows:

134 36. (Amended) A method according to claim 1, wherein said water is added to said micronized progesterone at rate of between about 6 to 9 ml per minute.

Kindly amend claim 40 to read as follows:

135 40. (Amended) A tablet prepared by the steps of:
slowly mixing water with micronized progesterone, the total amount of water mixed with said micronized progesterone not exceeding the maximum wetting capacity of the amount of micronized progesterone, whereby to obtain wetted micronized progesterone;
drying said wetted micronized progesterone to form dry micronized progesterone;
mixing said dry micronized progesterone with a pharmaceutically acceptable excipient or diluent therefor; and
forming a tablet by direct compaction of said substantially dry micronized progesterone which has been mixed with said pharmaceutically acceptable excipient or diluent therefor.

Kindly amend claim 41 to read as follows:

41. (Amended) A tablet prepared by the steps of:
slowly mixing water with micronized progesterone, the total amount of water mixed with said micronized progesterone not exceeding the maximum wetting capacity of the amount of micronized progesterone, whereby to obtain wetted micronized progesterone;
drying said wetted micronized progesterone to form dry micronized progesterone;
mixing said dry micronized progesterone with (a) a pharmaceutically acceptable non-effervescent excipient or diluent therefor and (b) an effervescent; and

135 forming a tablet by direct compaction of said dry micronized progesterone which has been mixed with said pharmaceutically acceptable non-effervescent excipient or diluent therefor and said effervescent.

Kindly add the following claims 46-54:

136 --46. (New) A method of delivering progesterone to a female patient, comprising placing in the vagina of said patient a tablet as recited in claim 40 and retaining said tablet in said vagina for a time efficacious to deliver said progesterone to said patient.

47. (New) A method according to claim 46, wherein said tablet contains at least 50 mg of micronized progesterone.

48. (New) A method of delivering progesterone to a female patient, comprising placing in the vagina of said patient a tablet as recited in claim 41 and retaining said tablet in said vagina for a time efficacious to deliver said progesterone to said patient.

49. (New) A method according to claim 48, wherein said tablet contains at least 50 mg of micronized progesterone.

50. (New) A method according to claim 48, wherein said placing of tablet is effected as part of a twice-daily dosing regimen.

Sub C 51. (New) A vaginally administrable tablet comprising micronized progesterone, a non-effervescent excipient or diluent therefor, and an effervescent.

136 52. (New) A method of delivering progesterone to a female patient, comprising placing in the vagina of said patient a tablet as recited in claim 51 and retaining said tablet in said vagina for a time efficacious to deliver said progesterone to said patient.

53. (New) A method according to claim 52, wherein said tablet contains at least 50 mg of micronized progesterone.

54. (New) A method according to claim 53, wherein said placing of tablet is effected as part of a twice-daily dosing regimen.--
